

EXPRESS MAIL MAILING LABEL

COPY



No. EL30264587745

PATENT
Atty. Docket No. CWP-012FW
(1451/2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): DAVID E. CHARLTON and NEAL W. MILLER

SERIAL NUMBER: 07/995,331 **GROUP NUMBER:** 1817

FILING DATE: Dec. 23, 1992 **EXAMINER:** Spiegel, C. A.

TITLE: TEST DEVICE AND METHOD FOR COLORED PARTICLE
IMMUNOASSAY

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being deposited with the receptionist of Art Unit 1817 and Examiner C. Spiegel At the US Patent and Trademark Office, Washington D.C., 20231 on:

Date: _____, 1997

(Print Name)

The Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

**DECLARATION OF DAVID E. CHARLTON, NEAL W. MILLER
AND MARGARET MAZZEO UNDER 37 C.F.R. 1.131**

We, David E. Charlton, Neal W. Miller and Margaret Mazzeo, hereby declare as follows:

1. Prior to March 27, 1987, we had actually reduced to practice, in the United States, a method for detecting, by visual observation of color development, the presence of a ligand in a liquid sample, i.e., the presence of human chorionic gonadotropin (hCG) in urine, which satisfies all of the limitations of the claimed subject matter in the above-captioned patent application as currently amended. As evidence of our reduction to practice, we attach as "Exhibit A" a true copy (except all dates have been redacted) of a page from a notebook of Margaret Mazzeo (née Verbanic), a scientist employed by the assignee of the instant application, Carter-Wallace, Inc.,

and who performed experiments under the direction of named coinventor Dr. Charlton. These experiments described the use of a device for detecting the ligand hCG according to the presently claimed invention. The original notebook page bears a date earlier than March 27, 1987, and refers to experiments completed as of an earlier date. (The date on the notebook page has been deleted on the copy submitted herewith.)

2. Exhibit A is a date-redacted copy of a notebook page entitled "New Chromatostrip Device-Tested Spiked Problem Urine" and documents a "preliminary evaluation" in which an experimental device was used. The device comprises a housing made of a pair of substantially rigid, water-impervious, rectangular planar plastic strips sandwiching an adsorbent test strip ("Eaton Dickman 111" sorbent material) laminated together by bonding tape. The housing has two windows (viewing holes passing through the top surface permitting visual observation of portions of the test strip), and an inlet (bottom part of the housing where the strip is exposed between the top and bottom housing surfaces). The sorbent strip material defines a flow path extending from the inlet to a test site comprising immobilized antibody specific for hCG (20 μ l of a solution of polyclonal antibody coupled to adhered latex particles) and to a control site (adhered latex particles coated with non-specific polyclonal antisera). As Exhibit A indicates, five urine samples were prepared, 250 μ l each spiked with 0, 25, 50, and 150 mIU, and 1 IU of hCG. Each urine sample was added to an amount (assay strength $OD_{525} = 0.375$) of lyophilized gold sol-hCG specific antibody (b105_{15nm}). Each reconstituted conjugate sample mixture was applied to the inlet of one experimental chromatostrip device as described above and allowed to flow along the flow path by sorption. Exhibit A illustrates the five experimental devices used in this experiment and shows the experimental results. A color is observed at each test site (top window) for samples containing the antigen and it develops darker as the concentration of hCG in the urine samples increases. A pale color is observed at the control site (bottom window) that remains constant in intensity and is independent of the concentration of hCG.

3. Exhibit A records an experiment which constituted a reduction to practice of the invention as currently claimed. The device operated to detect the ligand hCG in a liquid sample in accordance with the claimed method of the invention. To reiterate, the liquid sample suspected

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4. All statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: March 10, 1997

David E. Charlton
David E. Charlton, coinventor

Date: _____

Neal W. Miller, coinventor

Date: _____

Margaret Mazzeo, corroborating scientist

New Phorotship Device ~ Tested spiked problem urine

Materials: b105 15mm OD 525 750 ~ assay strength 375

fresh problem urine (MV)

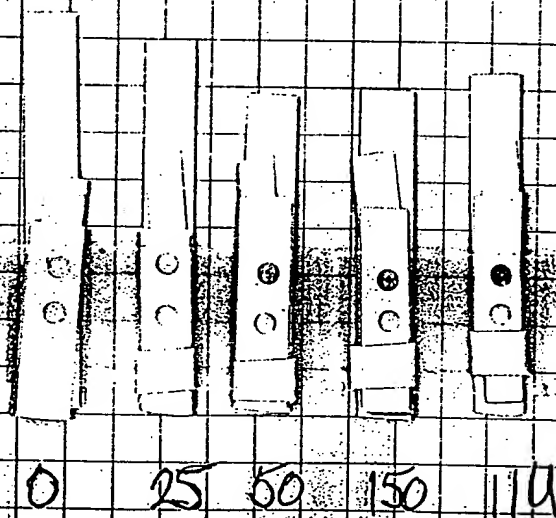
hcb Sigma lot #

25 50 150 mIU 1 IU

polyclonal latex CA

20ul spotted on Eaton Dickman III

Procedure: reconstituted or lyophilized conjugate with
250ul urine or blank or spiked
w/ hcb



Clinicals ~ Device with sample



EXHIBIT A

SIGNED

WITNESSED BY

DATE

DATE

M. Verbanic

EXPRESS MAIL MAILING LABEL

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APPLICANT(S): DAVID E. CHARLTON and ^{NEIL}~~NEAL~~ W. MILLER

SERIAL NUMBER: 07/995,331 GROUP NUMBER: 1817

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^{NEIL}
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Date: _____

David E. Charlton, coinventor

Date: MARCH 10, 1997



Neal W. Miller, coinventor

NEIL

Date: _____

Margaret Mazzeo, corroborating scientist

PURPOSE

New Chromatoship Device ~ Tested spiked problem urine

Materials

b105 15mm OD 525 750 ~ assay strength 375

fresh problem urine (mv)

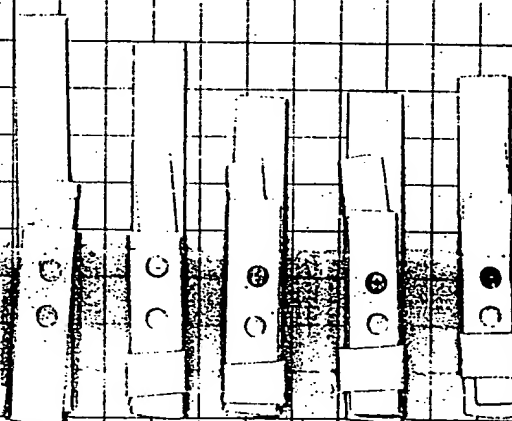
hcb Sigma lot #

25 50 150 ml 1 ml

polyclonal latex CA

20ul spotted on Eaton Dickman IIII

Procedure

reconstituted sta lyophilized conjugate with
250ul urine or blank or spiked
w/ hcb

0 25 50 150 1114

Clinicals

Device with sample



EXHIBIT A

SIGNED

WITNESSED BY

DATE

DATE

COPY COPY

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No. EL302645877US



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Date: _____

David E. Charlton, coinventor

Date: _____

Neal W. Miller, coinventor

Date: March 5, 1997

Margaret Mazzeo
Margaret Mazzeo, corroborating scientist

New Chromastrip Device ~ Tested spiked problem urine

Materials 6105 15mm OD 525 750 ~ assay strength 375

fresh problem urine (MV)

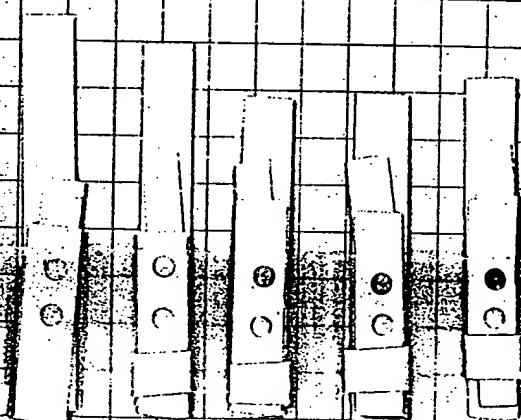
hcg (Sigma lot #)

25 50 150 mIU 1 IU

polyclonal latex CA

20ul spotted on Eaton Dickman III

Procedure reconstituted & lyophilized conjugate with
250ul urine or blank or spiked
w/ hcg



0 25 50 150 114

Clinicals ~ Device with sample



EXHIBIT A

SIGNED

WITNESSED BY

DATE

DATE

M. Verbanac